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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,227	11/12/2003	John D. Pruitt	029318-0985	3550

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
08/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/705,227	PRUITT ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 19-57* is/are pending in the application.

4a) Of the above claim(s) *27 and 31-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,19-26,28-30 and 37-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment and remarks filed 5/29/2009. Claims 1, 19, 37 and 57 are amended. Claims 1-17 and 19-57 are pending. Claims 27 and 31-36 are withdrawn from consideration.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-17, 19-26, 28-30 and 37-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murakami et al. (US 6,287,596) for reasons of record and reiterated herein below.

Murakami discloses fast disintegrating compression molded product/tablet (abstract; column 4, lines 24-63; column 7, lines 11-15) comprising pharmaceutically active agents listed

in column 5, line 61 to column 6, line 67 meeting the requirements of claims 1, 26, 30 and 56; for example, ibuprofen (column 6, line 3) is slightly or poorly water soluble meeting claim 52 and diphenhydramine hydrochloride (column 6, line 5) is soluble in water meeting claim 51, lubricants, diluents, coloring agents with the diluents being lactose or glucose or sucrose and the binders being acacia or pullulan or polyvinylpyrrolidone, flavoring agents, effervescent agents such as combinations of tartaric acid, malic acid and sodium carbonate or sodium bicarbonate (column 7, lines 13-45), and the pullulan and the effervescent couple meeting claims 1, 4, 5, 7-11, 14-16, 25 and 26 and 46. Claim 17 is the property of the product so that Murakami meets the claim. Friability is a property of the product; the disintegration time of the product of Murakami is in the order of seconds (column 9, lines 13-43) meeting claims 14 and 50; Murakami teaches that the rapidly disintegrating compression molded material is orally administered to infants and aged adults for the treatment of variety of diseases (column 9, lines 44-60; column 10, lines 34-40) meeting claim 37. Thus Murakami discloses a composition containing pullulan, effervescent couple, lactose and active agent. The composition of Murakami also contains surfactants (column 7, lines 43-49) meeting claims 21 and 28-30. Regarding claims 1, 19, 20 and 37 active agents are generally obtained in powder forms (column 5, lines 54 and 57) and the particles of the powder have sizes that meet the limitations of claims 18-20, with powder meeting the amorphous particle limitation of claim 55. The sugar alcohols in Murakami are namely D-mannitol, D-sorbitol, xylitol, maltitol, anhydrous maltose, hydrous maltose, anhydrous lactitol, hydrous lactitol, and reducing malt sugar syrup. Of these, D-mannitol, xylitol, and multitol (column 4, lines 54-58) and other excipients such as starches and celluloses (column 4, lines 29-53) meet claims 4-8, 11, 40, 41, 43, 44 and 47. Claim 48 is a

product by process claim such that Murakami meets the claim. Regarding the amounts of the active agent and surface stabilizer, the claims 22-24 would have been obvious because the ordinary skilled artisan have the capabilities to use desired amounts of active agents and surface stabilizers in the composition Murakami for a rapidly disintegrating material. No specific particle size is recited in Murakami except that the active agents are in powder forms prior to inclusion in the dosage form such that the powder would have small particles sizes. Therefore, taking the general teaching of the reference, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that using surface stabilizers and drugs in powder form and in appropriate and desired amounts would lead to solid dosage form that would have the anticipated rapid disintegration.

Response to Arguments

4. Applicant's arguments filed 5/29/09 have been fully considered but they are not persuasive.

5. Applicant argues that Murakami does not teach or suggest the concentration of pullulan or the friability of the composition considering that pullulan is optional in Murakami, that Murakami teaches quickly disintegrating compression molded composition with the active agent at 1-70% without imposing any particular limitation on the pharmaceutically active agent so that applicant argues that the examiner failed to establish inherency because the examiner failed to show proof that the claimed dosage form comprises at least one active agent and pullulan at a concentration of about 99.9% to about 0.1%.

6. The examiner agrees with the applicant in some respects and disagrees with the applicant in other respects and totally disagrees with the applicant that the claimed composition

comprising at least one active agent and pullulan at a concentration of about 99.9% to about 0.1%.

6 a) The examiner agrees with the applicant that binding agents such as pullulan, polyvinyl alcohol, acacia, dextrin and pectin are optional in Murakami (see column 7, lines 26-30) but Murakami also teaches that these "additives are usually used in the production of tablets so long as the effects of the invention are not impeded," (column 7, lines 13-16).

6 b) The examiner agrees with the applicant that Murakami does not specifically say how much binder can be used. But Murakami's silence as to the amount of the binder/pullulan to be used is an indication that any amount of binder can be used to effect proper dissolution and cohesiveness of the tablet. Thus the artisan in the tablet formulation art would use binders in amounts that would provide adequate table cohesiveness and dissolution considering that Murakami contemplates "tablets which exhibit rapid disintegration and dissolution when placed in the oral cavity or water and which do not collapse throughout the processes of manufacture and distribution" (see column 3, lines 54-57). However, formulation 4 on table 1 of Murakami uses about 1.25% polyvinyl pyrrolidone, which is one of the binders contemplated for use as a binding agent. Therefore, the artisan while being led to use binders in amounts that would be effective to produce the desired product that rapidly disintegrates and dissolves when placed in the oral cavity or water and which would not collapse throughout the processes of manufacture and distribution, would be guided by the formulation 4 of Table 1 to use at about 1.25%, which is one of the points in the continuum of about 99.9% to about 0.1%. With regards to the 1-70% active agent used in the Murakami art, it is noted that claims 1, 19, 37 and 57 do not recite amounts of active agent.

6 c) The examiner also agrees with the applicant that Murakami does not impose any particular limitation on the active agent, but in essence teaches that any of the active agents listed in column 6, lines 1-67 may be formulated into the quickly disintegratable compression molded dosage forms. Some of these agents are some of the many active agents recited in claims 26, 30, and 56.

6 d) Thus, Murakami strongly suggests formulating dosage form comprising at least one active agent and binding agent that can be pullulan, which can be used in amounts that provides the desired dissolution and disintegration of the dosage form.

6 e) Friability is a measure of the hardness of a tablet and a property of a given tablet. Murakami is clear that the composition must not collapse during manufacture and distribution (column 3, lines 56, 57) and should have high strength that does not permit collapse of the dosage form during manufacture and distribution (column 3, lines 61-63) and the goal of Murakami is to produce a dosage form that exhibits rapid disintegration and dissolution, but shows high hardness at the same time (see column 3, lines 52 and 53).

7. Therefore, the dosage form of Murakami comprising at least one active agent and binder such as pullulan in amounts that lie within the recited ranges in at least claims 1, 2, 19, 36, 38, 54 is inherently/expressly hard and less friable than the tablets of the prior art. Thus, a friability of less than about 1% is inherent property and the Murakami's dosage form which is contemplated to be hard inherently possesses low friability. Applicant has also not advanced any argument that friability is not a measure of the hardness of the tablet or provided any factual showing that the dosage form of Murakami crumbles during storage and/or distribution.

8. Applicant argues that active agent and pullulan are optional ingredients, but it is well settled that a references may be relied upon for all that it would reasonably have suggested to one of ordinary skill in the art that includes non preferred embodiments (see Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.). Furthermore, a reference disclosing optional inclusion of particular components teaches compositions that both do and do not contain that component (see Upsher-Smith Labs. v. Pamlab, LLC, 412 F.3d 1319, 1323, 75 USPQ2d 1213, 1215 (Fed. Cir. 2005). Thus, the composition of Murakami teaches compositions that contain or do not contain those optional ingredients.

9. Applicant further argues that the examiner has used improper hindsight to arrive at the claimed composition because Murakami provides optional inclusion of active agent and binders from which pullulan is selected. The examiner disagrees that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, because, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the present case, while active agent is disclosed to be optional in Murakami, active agents are specifically contemplated for inclusion in the formulation according to claims 13-16. Additives such as binders, lubricants and disintegrants are usually used for tablet production according to Murakami at column 7, lines 10-12. Pullulan is one of 14 binders disclosed in Murakami and any of the binders including pullulan can be used.

10. Applicant further argues that Murakami does not mention friability and that although, Murakami discusses hardness, "hardness and friability are two different parameters in determining mechanical strength of a solid dosage form, with no necessary correlation with each other," so that applicant argues that the disclosed "hardness" fails to render the claimed invention obvious. The examiner agrees with the applicant that Murakami does not use the term friability. The examiner also agrees with applicant's acknowledgement that Murakami discusses hardness of the formulation. In fact, Murakami's goal is to produce rapidly disintegrating and dissolving dosage form that is hard. However, the examiner disagrees with the applicant that hardness and friability are not correlated. While the examiner admits that hardness and friability have different units or measure, it is known that friability is as property of a tablet that is related to hardness as evidenced by the 18th edition of Remington's Pharmaceutical Sciences, Gennaro edited 1990 at 3rd full paragraph of the right column of page 1639. In general, the harder the tablet, the lower the friability of the tablet as evidenced by claim 1 and column 1, lines 15-18 of US 6,524,617. Therefore, the disclosed hardness renders obvious low friability properties.

11. No claim is allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Examiner, Art Unit 1618